

**Acceptability and feasibility randomized controlled trial of a digital psychological support intervention for people with Parkinson's disease: trial protocol**

Cathryn Pinto<sup>1</sup>, Jennie Brown<sup>1</sup>, Catherine Hurt<sup>1</sup>, Patricia Cubi-Molla<sup>2</sup>, Sulayman Chowdhury<sup>2</sup>, Lance McCracken<sup>3</sup>, Sam Norton<sup>4</sup>, Simone Stumpf<sup>5</sup>, Angeliki Bogosian<sup>1\*</sup>

<sup>1</sup>City, University of London;

<sup>2</sup>Office of Health Economics;

<sup>3</sup>Uppsala University;

<sup>4</sup>King's College London;

<sup>5</sup>University of Glasgow

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\*Corresponding author: Angeliki Bogosian, City University London, City, University of London, Northampton Square, London, EC1V 0HB, [Angeliki.bogosian.1@city.ac.uk](mailto:Angeliki.bogosian.1@city.ac.uk)

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## **Abstract**

**Background.** People with Parkinson's disease can experience psychological distress and have difficulties accessing face-to-face psychological support due to symptom burden and limited availability of psychological services. Digital options for psychological support can bridge this gap. We have developed an app based on Acceptance and commitment therapy (ACT) to support people with Parkinson's to improve psychological wellbeing.

**Aim.** To assess the acceptability of the app and the feasibility of conducting a randomised controlled trial (RCT) to evaluate the effectiveness of using the app to improve wellbeing for people with Parkinson's.

**Methods.** We will conduct a parallel-group randomised controlled feasibility trial comparing a digital app based on ACT (intervention group) to usual care (waitlist control group). We will recruit 60 people with Parkinson's, 40 to the intervention group and 20 to the control group. Primary feasibility outcomes include recruitment and retention rate, intervention engagement and satisfaction. Secondary outcomes include measures of clinical effectiveness (anxiety and depression), quality of life, and cost-effectiveness. Interviews will be conducted to assess acceptability of the app. Primary feasibility outcome data will be analysed descriptively and compared against pre-defined feasibility criteria. Secondary outcomes will be analysed based on an intention-to-treat principle and a cost-consequence analysis will be

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used to estimate cost-effectiveness. Interviews will be analysed using a deductive thematic analysis based on the Theoretical Framework of Acceptability.

Discussion. This trial will provide data on the feasibility of conducting a full-scale RCT of the effectiveness and cost-effectiveness of the app to improve psychological wellbeing for people with Parkinson's disease.

**Key words**

Parkinson's Disease, psychological intervention, app, Randomised Controlled Trial, Acceptance and Commitment Therapy

## **Introduction**

Parkinson's disease is a neurodegenerative disease that can lead to a wide range of motor and 'non-motor' symptoms. People with Parkinson's (PwP) frequently experience a range of psychological issues including anxiety, depression, and apathy (1). Receiving a diagnosis of Parkinson's and having to cope with the unpredictable and debilitating symptoms can also have a psychological impact on individuals (2). The prevalence of anxiety among PwP can be as high as 50-55% (3,4) and 50-56% for depression (2,4).

A number of psychological interventions have been developed to support PwP. Cognitive behavioural therapy (CBT) has been most frequently used in research and shown to be effective in treating depression and sleep problems in PwP (5). Some research has also been conducted using other therapeutic approaches. For example, there is some evidence to suggest that interventions using mindfulness and acceptance and commitment therapy (ACT) may be beneficial to improve wellbeing (6,7). However, research is limited and there is a clear need to understand more about how these approaches can be used to support PwP (5). Acceptance and Commitment Therapy (ACT) is an empirically-based psychological intervention that focuses on personal growth and the cultivation of wellbeing through enhanced psychological flexibility (8). A recent review revealed that participants' well-being was significantly higher in ACT intervention groups than control groups in all but one study in adult clinical and non-clinical populations (9). Most of these studies revealed moderate effect sizes in favour of ACT. There is some evidence that ACT interventions effectively support mental health even when delivered online as microlearning (10), but there is limited research on the use of ACT with PwP.

Despite promising research evidence, few psychological therapies have been implemented in clinical practice and the current provision for mental health support for PwP is not adequate (11). Most PwP have little access to psychological support because support is time- and resource-intensive. Additionally, mobility limitations, travel burden and cost can

make psychological therapy inaccessible for many PwP and this lack of access intensified during the COVID pandemic (12). As a response to the need for accessible, less resource intensive interventions, the use of digital applications to provide mental health support has grown in recent years (13). With Parkinson's, there has been some research using remotely delivered interventions such as CBT and mindfulness and this was found to be suitable and acceptable to PwP (6,14–17). Therefore, digital interventions could be a promising approach for psychological support for PwP.

There has not yet been any research using digital applications known as 'apps' to deliver psychological support for PwP (18). Although this can be a feasible format it may also come with certain challenges. Parkinson's symptoms such as tremors and hand/finger dexterity can make it difficult for PwP to access and use electronic devices and programs that are not designed with accessibility in mind. Similarly, symptoms such as speech difficulties and difficulties with facial expressions may also limit the use of certain features like voice and facial recognition. The design of any digital solution for PwP needs to be made with these accessibility issues in mind. The activities or suggestions within the intervention or app also need to consider this variability in Parkinson's symptoms and levels of ability. The need for digital psychological interventions to be sensitive to physical symptoms and accessibility has been previously highlighted in other similar neurodegenerative conditions (19–21).

Due to the promising evidence in support of digital approaches to provide psychological support for PwP, we developed a self-guided digital app based on ACT for PwP. To take into account potential issues with acceptability and accessibility, we developed the app through a co-design process that integrated users' views and feedback in the development and optimisation of the app. In this study, we will assess the acceptability of the app and the feasibility of a trial to evaluate this digital app to improve psychological wellbeing in PwP. We aim to determine whether a larger RCT examining clinical and cost-effectiveness is warranted.

Research objectives:

- (1) To assess the feasibility of trial procedures and methods, based on a) recruitment rate, b) retention rate, c) contamination rate, and d) adherence rate.
- (2) To describe patterns of app usage and engagement in terms of a) frequency and duration of app use overall b) rates of engagement with individual elements.
- (3) To provide preliminary assessments of the treatment effect on primary and secondary outcomes
- (4) To provide a preliminary assessment of the cost-effectiveness of the intervention
- (5) To assess satisfaction with and acceptability of the app for improving psychological wellbeing in people with Parkinson's.

## **Method**

### *Design*

We will conduct a parallel-group, non-blinded, randomised controlled feasibility trial comparing a digital app based on ACT (intervention group) to usual care (waitlist control group). The trial was registered on the ISRCTN clinical trials registry, number ISRCTN65177345.

### *Participants*

#### *Sample size*

We will aim for a total sample size of 60 PwP (40 PwP in the intervention group and 20 PwP in the control group). As this is a feasibility trial the sample size is based on precision of the key variables informing the feasibility decision (objective 1), rather than a formal power calculation. A target sample size will allow us to estimate the recruitment rate out of all of those assessed for eligibility with a 95%CI (binomial exact) with precision (i.e., width) of  $\pm 10\%$ , assuming a 60% rate based on previous studies with similar recruitment (ref), and higher precision (i.e. narrower 95%CI) if the rate is lower than anticipated. Furthermore, we will be able to estimate retention rates with a 95%CI (binomial exact) with precision (maximum width) of  $\pm 12\%$ . Rates of contamination and adherence in the intervention group will be estimated with a 95%CI (binomial exact) with precision (maximum width) of  $\pm 16\%$

#### *Inclusion and exclusion criteria*

Participants will be screened for inclusion based on the following criteria:

Inclusion criteria:

- Age: 18 years and above

- Self-reported diagnosis of Parkinson's
- Lives in the UK
- Has access to computer/tablet/smartphone and the internet
- Is able to read and communicate in English
- Be stable on anti-depressants or anxiolytics if taken- stable dose for a minimum of 1 month
- Mild-to-moderate levels of distress determined by a score between 3-8 on the PHQ4.

Exclusion criteria:

- Severe cognitive impairment as determined by a score of 20 or above on the 6-item Cognitive Impairment Test (22).
- Psychiatric conditions (e.g., psychosis, drug/ alcohol addiction) that can potentially risk failure in the treatment or limit participation in the course.

## ***Procedure***

### *Recruitment and screening*

We will recruit participants through the Parkinson's UK research support network via newsletters, social media, and local groups. The study advert through Parkinson's UK will direct potential participants to contact a member of the research team who will then arrange a phone call with potential participants. During this call, the researcher will ask participants some screening questions based on the eligibility criteria and answer any questions participants may have about taking part. Participants will then be informed of their eligibility to take part. Those who are not eligible will be provided with additional information and resources where

appropriate. Eligible participants will be emailed the participant information sheet and links to complete the consent form and baseline questionnaire.

### *Randomization and blinding*

Following completion of the baseline questionnaire, participants will be randomly allocated to two groups – 40 participants to the intervention group and 20 to the control group (see Figure 1). Randomisation will follow a 2:1 ratio stratified by disease impact and baseline levels of psychological distress, using variable block sizes. This will be undertaken using an online system called Sealed Envelope ([sealedenvelope.com](https://sealedenvelope.com)). The participants will be blind to their group allocation at the time of randomisation. Once participants are allocated to either the intervention or waiting list, both participants and the research team (except for the statistician) will be aware of group allocations.

The control group will be sent an email with links to information about mental health from the Parkinson's UK website (<https://www.parkinsons.org.uk/information-and-support/parkinsons-and-mental-health>) and instructions for continuing to take part in the trial.

At the end of 4 weeks, both intervention and control groups will be sent an email with instructions to fill in the endpoint questionnaire. Participants from the intervention group will also be invited to take part in an interview.

[Insert Figure 1 about here]

### *Intervention group*

After completing the baseline questionnaire, intervention group participants will be sent a link to access the app along with instructions and log in details by a member of the research team via email. Participants will be requested to use the app regularly for a 4-week period. At the end of 4 weeks, participants will fill in an endpoint questionnaire measuring outcomes and

satisfaction with the app. They will also fill in a healthcare utilisation questionnaire and be offered the opportunity to take part in an interview. Participants in the intervention group will be able to contact a member of the research team if they experience any technical difficulties using the app during the trial period.

#### *Waitlist control group*

Participants allocated to the control group will receive the care they would usually expect within the NHS. This is typically in secondary care with a specialist neurology team according to individual health needs. The individual may be supported in the NHS by a multidisciplinary team including neurologists, physiotherapists, occupational therapists, speech and language therapists and Parkinson's specialist nurses. The patient and carer may also be offered or introduced to support from a charity called Parkinson's UK. In addition, as these were participants who had some level of psychological distress, they will be sent a link with information about mental health from Parkinson's UK website (<https://www.parkinsons.org.uk/information-and-support/parkinsons-and-mental-health>).

After 4 weeks, they will be sent an endpoint questionnaire (measuring outcomes only) and a healthcare utilisation questionnaire. Control group participants will be offered a chance to use the app after the 4-week trial period and endpoint questionnaire has been completed.

#### *Intervention*

The intervention group will be emailed a link (along with a username and password) that gives them access to the app and an informational video demonstrating how to use the app. On first use, they can change the password, and set up their profile. Except for participant first names, all other personal details are kept separate from any application data for security and privacy purposes. Reminders are sent to participants to prompt session completion and encourage

regular app use. Participants are also asked to set their main reason for using the app and are reminded of this to motivate continued app use.

The app contains a toolkit of sessions based on ACT. The aim of the intervention is to improve psychological wellbeing by increasing psychological flexibility in PwP so that they are open and accepting of their thoughts and feelings, struggle less with these thoughts and feelings, learn to connect with the present moment, and engage in more value-based activities. The aim is for the app to be used as a stand-alone intervention without any therapist support or facilitation.

Sessions are designed to be delivered as micro-content (i.e. 5-10 minutes bursts of content) that participants can complete in a short time period and at their own pace and convenience. The sessions are delivered via audio, video and text format, and encourages reflection and practice from participants. Reflections can be input as text or voice-recorded. At the end of each session, participants are asked to rate the session they have completed. After every 6 sessions, participants are asked to review their progress and practice in relation to the processes of being open, aware, and engaged through a 6-item progress questionnaire.

The first 12 sessions are guided, standardised sessions for all participants. The purpose of these sessions is to introduce participants to the key processes of ACT – open, aware, engage through providing information, metaphors and experiential activities. After 12 sessions, participants can use the app in two ways – one path provides session recommendations and the other path allows participants to choose sessions based on their own judgement of needs and preferences. Session recommendations are made using a combination of results from participants' session ratings and the responses to the 6-item progress questionnaire. Visuals are used to display and reward session completion and progress.

The intervention has been designed through a series of co-production workshops. Researchers used a combination of the PERCEPT method and the person-based approach to inform the development process (23,24). The PERCEPT method guided the content and discussions of the co-production workshops and used personas to inform the design of the app. The person-based approach was used to keep users' needs and context at the heart of intervention development. Literature reviews and experiences of workshop participants were used to develop the plan for the intervention and guiding principles. Drafts of the app content and design were presented to participants, changed iteratively and recorded using a table of changes. The app prototype was presented to participants during the workshop and feedback was incorporated into the final version. This app was also beta-tested with users before developing the final version for the trial.

### *Assessments and outcome measures*

Several assessments and outcome measures will be collected at each stage of the study from screening to baseline, during the trial and post-intervention (see Figure 2 for a summary).

[Insert Figure 2 about here]

At baseline, the following demographic and clinical data will be collected from both intervention and control groups: age, gender, ethnicity, education, work status, diagnosis, medications, Parkinson's duration, symptoms and severity, familiarity and comfort with using technology.

### *Primary feasibility outcomes*

Primary feasibility outcomes for the trial include the recruitment rate (proportion of people identified as eligible after screening, and proportion of eligible people randomized/consented to the study) and retention rates (proportion of people who completed the baseline and endpoint assessments), adherence rates (number of times logged on to the app and number of sessions completed), contamination rates (proportion of people in the control who receive an intervention expected to impact the primary outcome) and data completeness (missing data from baseline and endpoint questionnaires).

#### *App usage and engagement*

Description of the sessions completed (number and type), session ratings, pattern of engagement (i.e. frequency, time of day), and a description of the different app features used by the participants (for example, session reflections, motivations, progress questionnaires) . This data will be logged automatically as participants use the app.

#### *Secondary outcomes*

*Effectiveness.* To inform the selection of outcome measures for a full RCT, the following measures will be administered to all participants at baseline and endpoints:

1. Depression – PHQ-9. The PHQ-9 (25) is a 9-item measure of depression symptoms based on the DSM-IV criteria for depression. Participants rate each item on a 4- point scale between 0 (not at all) and 3 (nearly every day). The PHQ-9 is sensitive to change and has demonstrated reliability and validity as a measure of depression symptoms (25).
2. Anxiety – GAD-7. This is a self-administered patient questionnaire used to measure the severity of anxiety. It is a 7-item scale and has good reliability, as well as criterion, construct, factorial and procedural validity and has been efficient at assessing generalised anxiety disorder in clinical practice and research (26).

3. Quality of life – PDQ-8. This is a patient-reported outcome measure widely used to quantify quality of life in people with Parkinson’s disease (27). It has 8 items and measures 8 dimensions – mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort – that have been psychometrically tested for PwP (28). PDQ-8 has been proven to be a very strong predictor of the full version PDQ-39 scores (29).
4. ACT variables:
  - a. Acceptance and avoidance questionnaire AAQ-2 – This is a short 7-item, general measure of experiential avoidance (30).
  - b. Experiences questionnaire (31) - This is a 14-item scale to measure decentering or the ability to observe one’s thoughts and feelings in a detached manner. Participants rate statements on a scale from 1 (never) to 5 (all the time). Higher scores represent greater decentering.
  - c. Committed actions questionnaire - CAQ-8. The CAQ-8 is a measure of committed action, which describes the degree to which individuals continue to flexibly pursue valued goals in the presence of challenges, a key treatment process of ACT (32,33).

*Treatment satisfaction and acceptability.* Acceptability with the intervention will be assessed via a short 8-item questionnaire based on the theoretical framework of acceptability (34), along with space for open-ended responses if participants want to give further feedback.

We will conduct in-depth interviews with up to 20 PwP who used the app to gather feedback on their experiences. At the end of the trial period a researcher will conduct qualitative interviews over the phone or via videocall to gather feedback about participants’ experiences using the app. Participants who have dropped out of the intervention group will also be invited to take part in the interviews. Purposive sampling will be used to identify our sample from the

intervention group to ensure we interview participants with a variety of demographic and clinical characteristics such as age, gender, symptoms, illness severity, disease duration, and participants who were highly engaged and minimally engaged with the intervention.

Interviews will take place between week 4 and 6. Participants will be asked questions around the acceptability of the app and their experience of using the app and associated ACT activities. The interview schedule and questions will be based on the theoretical framework of acceptability (34). This framework consists of 7 constructs – affective attitude (attitude towards the intervention), burden (reasons for discontinuation/drop out, amount of effort required), perceived effectiveness (extent to which the intervention can achieve its purpose), ethicality (extent to which the intervention fits with the individual's values), intervention coherence (extent to which the participant understands the intervention and how it works), opportunity costs (extent to which benefits or values are given up to undertake the intervention), and self-efficacy (confidence that they can perform behaviour required for the intervention).

*Healthcare resource utilisation.* The PD REHAB Healthcare Usage Questionnaire (35) will be administered to participants in the intervention and control groups at both baseline and endpoints. This questionnaire will measure variables such as healthcare professional consultations or visits and health aids and equipment used one month before and during the trial period. The results will inform the economic evaluation of the intervention.

### ***Feasibility criteria***

We will consider it appropriate to proceed with an RCT if:

- (1) We can a) recruit 60 ( $\geq 100\%$ ) and b) retain 40 ( $>66\%$ ) participants during the trial period (recruitment and retention).

- (2) If more than 70% of the intervention group log in to the app and complete at least one session.
- (3) If more than 50% of the intervention group participants rate their overall acceptability with the app and perceived usefulness for health and wellbeing above the midpoint.

We will decide to amend the intervention or trial procedures, and then proceed with an RCT if:

- (1) We can recruit 50 participants and retain 50% of those recruited.
- (2) If between 50-70% of the intervention group log in to the app and complete at least one session.
- (3) If 30-50% of the intervention group participants rate the overall acceptability and perceived usefulness for health and wellbeing above the midpoint.

We will not proceed with an RCT if:

- (1) We are unable to recruit more than 40 participants and retain 20% of those recruited.
- (2) If less than 50% of the intervention group log in and complete one session
- (3) If less than 30% of intervention group participants rate the overall acceptability of the app and perceived usefulness for health and wellbeing above the midpoint

These indicators were developed based on consensus between the research team who have experience in conducting trials and agreed before conducting the feasibility trial and through reviewing criteria used in other feasibility trials with similar populations.

### ***Data analysis***

#### *Primary and secondary outcomes*

The feasibility outcomes will be described – percentages and proportions of people screened, recruited, retention and dropouts, number of people who engaged with the app at different levels, and proportion of missing data. Analysis of secondary outcomes will be conducted following the intention-to-treat principle by a statistician (blind to treatment allocation). Treatment effects on the primary and secondary outcomes will be estimated using linear mixed-effects models with random-effects accounting for repeated observations within individuals. Covariates will include dummy coded treatment group indicator, dummy coded assessment time indicator, time-by-group interaction terms, the baseline level of outcome, physician assessed certainty of diagnosis, and any variables included as stratification factors in the randomisation procedure. Contrasts based on the model estimates will be used to compute point estimates with 95% CIs relating to treatments effects for the intervention arm versus the control arm. Mediation analyses will also help determine whether any changes in process variables mediate the effect of the treatment on the outcomes. Sensitivity analyses will also be undertaken to explore the impact of assumptions around missing data and adherence to the treatment protocol on the treatment effect for the primary outcome.

#### *Treatment satisfaction and acceptability*

Treatment satisfaction will be analysed descriptively, and a content analysis will be used for responses to open-ended questions. The interviews assessing intervention acceptability and changes experienced will be audiotaped, transcribed, and analysed using a deductive thematic analysis based on the Theoretical Framework of Acceptability (TFA) domains i.e. affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.

#### *Cost-effectiveness*

This study will aim to run a cost-consequences analysis of the PACT-am app use, informing decision-makers for a potential roll-out of the intervention. The cost-consequence analysis will be carried out using NICE's Medical Technologies Evaluation Programme (MTEP) model template, to maximise interpretability for NHS stakeholders and the efficiency of any future submissions. Clinical effects will be measured using the Parkinson's Disease Questionnaire short form (29), which is the reference instrument to measure quality of life in PwP (28,36). A mapping algorithm will also be applied to obtain EQ-5D-3L (European Quality of Life 5 Dimensions 3 Level Version) utility values (37). This measure is an estimate of quality of life regardless of the disease being investigated. This will ensure that the clinical evidence is able to meet potential future requirements for a cost-utility analysis as part of the evolving MTEP appraisal process and maximise flexibility to use the clinical evidence for other purposes.

### ***Data protection and management***

Before launching the app, we will conduct a data protection impact assessment and work through issues around data protection and sharing between the research team at the University of Glasgow and City University of London. Data related to the trial and participant data (contact details, demographics, outcome measures) will be retained and managed at City University. The research team at the University of Glasgow will collect data around app usage and engagement and this will be shared with the research team at City University in a de-identified format.

Participant's email addresses will be retained to inform them of the outcome of the study and will then be deleted. Data regarding participants who have been screened will be stored by the research team at City University and deleted after analysis for feasibility outcomes is complete. Participants who have consented to take part in the study will be given

a participant ID. Baseline and endpoint questionnaires will be linked to this ID, collected online via Qualtrics, and stored securely at City University. All anonymised participant data will be held in a repository for future use, in accordance with Parkinson's UK data sharing and preservation policy and guidelines. Ethical approval will be obtained from the City, University of London. Data sharing agreements between the universities involved in the project will ensure data is shared in a confidential and secure manner.

### ***Ethical considerations***

Participants who indicate a high level of distress (in relation to PHQ-9 and GAD-7) on the baseline and endpoint questionnaires will be contacted and asked if they need any further assistance and would like us to pass on their details to their neurology team. Participants in the intervention group will be prompted by email when they sign up to report any serious adverse events, for example suicidal thoughts, hospitalizations, worsening of mental health issues and life-threatening events during the trial period.

### ***Patient and Public Involvement (PPI)***

The intervention was co-designed with 7 PwP and 3 carers. The app was further user tested with PPI members before the start of the trial. 3 PPI members were actively involved in the project right from the conception of the project and the intervention idea to the app development process, and the design and conduct of the trial to evaluate the app. In terms of the feasibility trial, PPI members helped with the design of study including providing advice on recruitment procedures, study materials, questionnaires, interview topic guides, piloting procedures. We will also collaborate with PPI members regarding trial progress, interpretation of findings, lay summaries, and dissemination activities.

## **Discussion**

The trial data will determine if the trial design and procedure is feasible, including feasibility of recruitment and treatment completion. We will use primary feasibility outcomes in combination with interview data around intervention acceptability and experience to make modifications to either the intervention or the trial design for further evaluation in a randomised controlled trial. Examining the patterns of app usage and understanding changes experienced from using the app will help us make decisions around appropriate/recommended intervention dose and intervention duration. Data on feasibility outcomes and intervention acceptability will help us determine if a full-scale trial of effectiveness and cost-effectiveness is warranted.

ACT interventions delivered via digital formats have shown to have significant effects in improving outcomes for people with chronic pain (Rickardsson et al, 2020) and we would anticipate that our intervention would also improve psychological outcomes for people with Parkinson's. One limitation of the study is the short time frame and effects on psychological outcomes may need more time and more practice. In a larger randomised controlled trial, we can modify the treatment duration and length of follow up based on the findings from this study. We will also measure ACT processes and estimate if the intervention has an effect on the treatment mechanisms. The information from this study will also be useful for us to refine and select appropriate outcomes for a larger randomised controlled trial.

The app was designed using co-production and user-centred methods with people with Parkinson's. We hope this will improve the relevance and acceptability of the intervention; however, it is still important to test intervention acceptability when participants use the intervention over a period of time. We have adopted a mixed methods approach to understanding participants views and experiences using the intervention. This is a strength of

the study and will provide relevant data to improve the intervention or make recommendations for further intervention development in this area. Recruitment is expected to be completed by February, 2024 and the feasibility trial data analysed around April 2024.

**Disclosure statement:** The authors report there are no competing interests to declare.

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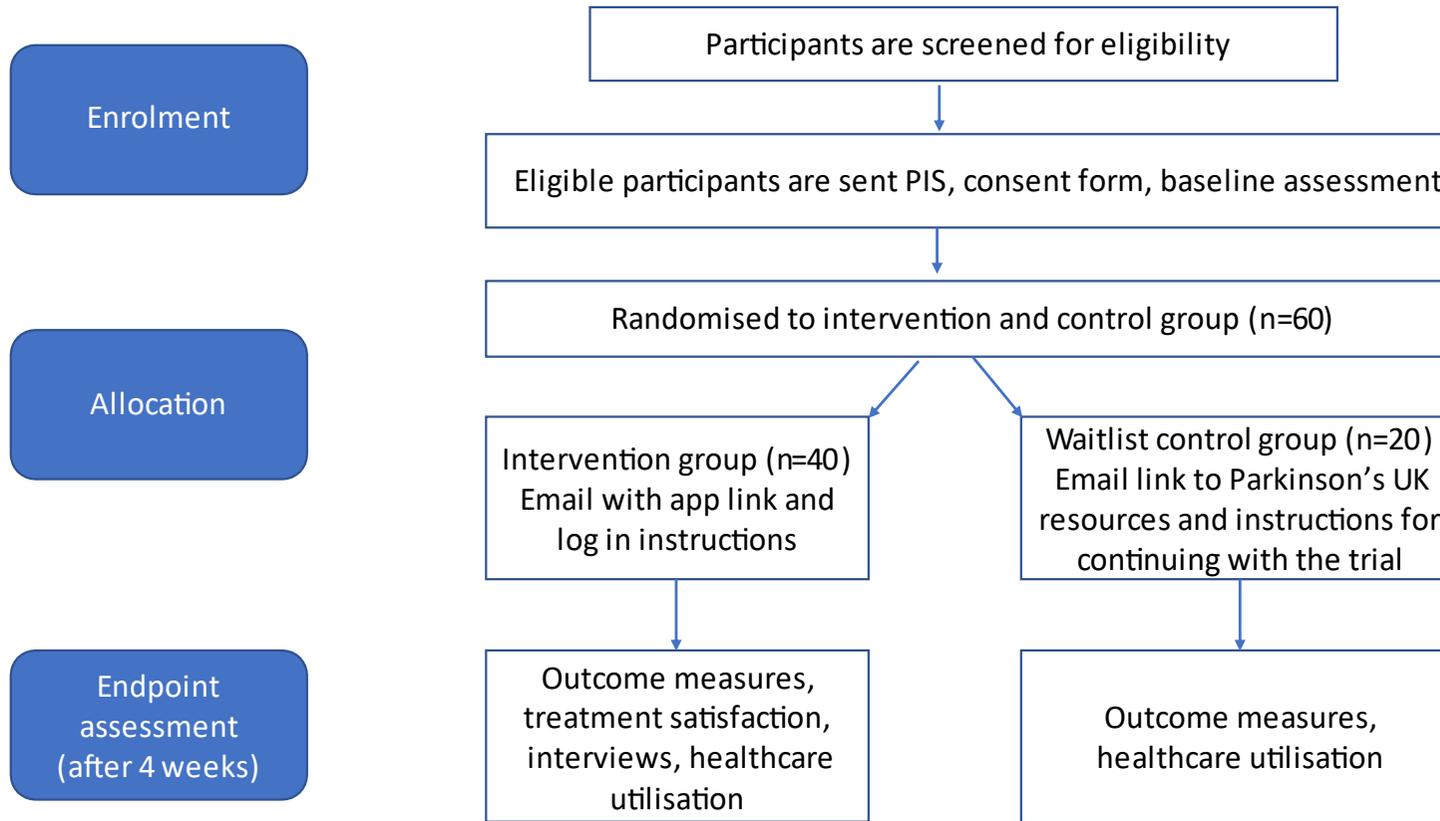
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**Figures**

**Figure 1. CONSORT Diagram**



**Figure 2. Summary of variables collected at different stages of the trial**

